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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/880,573	06/13/2001	Shintaro Suzuki	27866/37501	8090

4743 7590 07/19/2004

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EXAMINER

ROMEO, DAVID S

ART UNIT PAPER NUMBER

1647

DATE MAILED: 07/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/880,573	Applicant(s) SUZUKI, SHINTARO	
	Examiner David S Romeo	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 1-17, 19, 20 and 23-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18, 21 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-28 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 May 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed 05/10/2004 has been entered. Claims 1-28 are pending.

Applicant's election without traverse of claims 18, 21, 22, to the extent that they are drawn to a pc3 specific antibody, in the paper filed 09/26/2003 is acknowledged. Claims

5 1-17, 19, 20, 23-28 are withdrawn from further consideration pursuant to 37 CFR

1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the paper filed 09/26/2003. Claims 18, 21, 22 are being examined only to the extent that they are directed an antibody substance specific for protocadherin pc3.

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Maintained Formal Matters, Objections, and/or Rejections:

Claim Rejections - 35 USC §§ 101 and 112

Claims 18, 21, 22 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established

15 utility.

Applicants argue that the claimed antibodies are useful for purifying pc3, identifying tissue or cellular expression of pc3, and also as antagonists of protocadherin binding activities; that an antibody to an unknown cell surface protein has substantial utility as recognized by one of ordinary skill; that it is well established that antibodies are

20 useful for protein purification and localization; that it was well established at the time of filing that protocadherins mediate cell-cell interactions; that an antibody to a protocadherin is useful in isolating and modulating protocadherin activity; that the art

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provides a basis for a substantial and credible utility for the claimed antibodies.

Applicant's arguments have been fully considered but they are not persuasive.

The claimed invention lacks utility because the pc3 protocadherin, to which the claimed antibodies bind, is not supported by either a specific and substantial asserted

5 utility or a well established utility. In the absence of either a specific and substantial asserted utility or a well established utility for the polypeptide there is no patentable utility for the antibody that binds the polypeptide. The polypeptide is not supported by either a specific and substantial asserted utility or a well established utility because the specification provides little beyond its amino acid sequence (see Example 4). The

10 specification does not disclose a pc3 specific activity. Furthermore, Suzuki (U) indicates that it appears that protocadherins do not have a role in typical cell-cell adhesion (page 2610, right column, full paragraph 2). Recent studies have proved the cell adhesion role of classical cadherins in embryogenesis. In contrast, the biological role of protocadherins is elusive. Circumstantial evidence, however, suggests that protocadherins are involved

15 in a variety of cell-cell interactions. Protocadherins have unique properties. See Suzuki (U), Abstract. Circumstantial evidence suggest that they play an important role in vivo, but not much is known about their function (Suzuki (U), page 2611, left column, full paragraph 1). The evidence of record shows that members of the protocadherin family of polypeptides do not share a specific, substantial functional attribute or utility, despite

20 having structural features in common, and that membership in the protocadherin family of polypeptides does not impute a specific and substantial utility to the pc3 protocadherin. In the absence of either a specific and substantial asserted utility or a well established utility for the pc3 protocadherin, use of the claimed antibodies for the detection, isolation,

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localization, quantification, or purification of pc3 amounts to basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved, assaying or identifying a material that itself has no "specific and/or substantial utility," or making a material that itself has no specific, substantial and credible utility. These are examples of situations that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use and, therefore, do not define "substantial utilities." To argue that all antibodies have utilities that are well established and that, as a result, one of ordinary skill in the art would immediately appreciate why the claimed antibodies are useful, is not a utility specific to the claimed antibodies. At the time of Applicants' invention, the work required to confer value, hence patentable utility on pc3 and antibodies directed thereto, remained to be done.

Claims 18, 21, 22 are also rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. As Applicants recognize, a rejection under § 112, first paragraph, may be maintained on the same basis as a lack of utility rejection under § 101. A deficiency under 35 U.S.C. 101 also creates a deficiency under 35 U.S.C. 112, first paragraph. If the application fails as a matter of fact to satisfy 35 U.S.C. § 101, then the application also fails as a matter of law to enable one of ordinary skill in the art to use the invention under 35 U.S.C. § 112. A 35

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U.S.C. 112, first paragraph, rejection should be imposed or maintained when an appropriate basis exists for imposing a rejection under 35 U.S.C. 101.

New Formal Matters, Objections, and/or Rejections:

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Drawings

The drawings were received on 05/10/2004. These drawings are not acceptable.

In addition to Replacement Sheets containing the corrected drawing figure(s), applicant is required to submit a marked-up copy of each Replacement Sheet including annotations indicating the changes made to the previous version. The marked-up copy must be clearly labeled as "Annotated Marked-up Drawings" and must be presented in the amendment or remarks section that explains the change(s) to the drawings. See 37 CFR 1.121(d). Failure to timely submit the proposed drawing and marked-up copy will result in the abandonment of the application.

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Response to Amendment

The amendment filed 05/10/2004 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the change of the EC3 amino acid at position 261 from tyrosine to threonine, and the change of the EC5 amino acid at position 481 from phenylalanine to tyrosine. These changes are not supported by Miyatani et al. (Science. 1989 Aug 11;245(4918):631-5).

Applicant is required to cancel the new matter in the reply to this Office Action.

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Conclusion

No claims are allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

5 A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any
10 extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

15 ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (571) 272-0890. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M. IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, BRENDA BRUMBACK, CAN BE REACHED ON (571)272-0961.

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE FOLLOWING TC 1600 BEFORE AND AFTER FINAL RIGHTFAX NUMBERS:

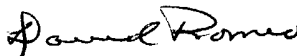
BEFORE FINAL (703) 872-9306

AFTER FINAL (703) 872-9307

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (571) 273-0890.

25 ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

30 

DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

35 DSR
JULY 14, 2004